UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,693	05/26/2000	Masaya Yamanouchi	0020-4710P	9841

2292 7590 05/18/2009
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
05/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MASAYA YAMANOUCHI, AKIO HONDA,
HIROMI HASE, TAKESHI SUGAYA and KENJIRO KIMURA

Appeal 2008-6229
Application 09/578,693
Technology Center

Oral Hearing Held: April 21, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

CRAIG A. McROBBIE, ESQUIRE
Birch, Stewart, Kolasch & Birch, LLP
8110 Gatehouse Road
Suite 100E
Falls Church, Virginia 22040-0747

The above-entitled matter came on for hearing on Tuesday, April 21, 2009, commencing at 12:59 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Dawn A. Brown, Notary Public.

P R O C E E D I N G S

THE USHER: Good afternoon. Calendar Number 32, Appeal Number 2008-6229. Mr. Robbie [sic].

JUDGE SCHEINER: Good afternoon.

MR. McROBBIE: Good afternoon. Let's clarify my last name is McRobbie.

JUDGE SCHEINER: Oh, okay.

MR. McROBBIE: But Robbie is fine.

JUDGE SCHEINER: All right. It is on here correctly.

MR. McROBBIE: I know we record it now. So the client might wonder why we sent somebody other than who we said we would send.

Okay. As for name changes, I wanted to clarify that although we indicated that the party in interest is Tanabe Seiyaku, in fact, they've had a merger, and they're now known as Mitsubishi, Tanabe, Pharma Corporation. Still the same company but they've merged in with another company. Just so we clarify.

JUDGE SCHEINER: Okay.

MR. McROBBIE: Okay.

JUDGE SCHEINER: Whenever you're ready, you can start. You have 20 minutes.

MR. McROBBIE: Excellent. Thank you very much.

I think I'd like to start off with a real quick summary, and I'm not sure exactly how much you want, but a real quick summary of the technology that is involved with respect to the claims at issue.

We have two independent claims, and those claims are claim 16 and claim 24, which can be seen in our appendix, pages 36 and 37, of the appeal brief. I'll read claim 16 real quick and then I'll come back and highlight --

JUDGE SCHEINER: We do have the claim in front of us.

MR. McROBBIE: Excellent. So without having to read it, the particular aspect of this claim which is of significance is the step B, detecting liver-type fatty acid binding protein contained in a specimen, and the preamble, a method for diagnosis or prognosis of a kidney disease.

So I want to highlight now, and then within the next 20 minutes, continue to highlight this connection between the diagnosis and prognosis of kidney disease.

And this particular marker, this liver type where we say L-fatty acid binding protein, L-FABP. Okay? And we're going to see that there are other types of FABPs that are known in the art.

But to back up real quick, obviously, diagnosis and prognosis or providing a patient with a reasonable idea of the progression of the kidney disease is important. But the main reason it is important, especially in the context of our L-FABP, is that early detection of these types of kidney diseases can actually be made.

Prior to the invention, it was difficult for patients to be diagnosed early simply because by the time they were referred to a nephrologist, in fact, it was too late. They were too far into the disease.

So what is happening with utilization of this L-FABP as a marker and tying that to the particular diagnosis or prognosis of kidney disease, in fact, we can push that timeline back to where, in fact, it is reasonable with proper

monitoring to diagnose patients early on when, in fact, steps can still be taken to either prolong their life or even reverse the damage that has already been caused.

Prior to that, patients were simply referred to the specialist too late to do anything. And so, in fact, there was this persistent and recognized need for a long time, if I can say a long-felt need, for this type of test. Okay?

So moving forward, now, we have this test and the issue is, is it, in fact, patentable? Is the test or the diagnostic test defined in claim 16 and to an extent in claim 24, is it patentable? The Examiner feels, in fact, it is not. The Examiner has said the claims at issue are prima facie obvious over a series of references, three references.

And I'd like to start off by talking about those references. I'm going to have to talk about them individually, but I want everyone to appreciate that, in fact, they all have the same deficiency, which I'll highlight it again, is the tie between L-FABP and this diagnosis or prognosis of kidney disease. So you're going to hear kidney disease and L-FABP, this liver-type fatty acid binding protein.

JUDGE GRIMES: Before we leave the claims. The preamble of claim 16 says a method for diagnosis or prognosis. So if you're diagnosing kidney disease, that doesn't necessarily require the person tested to have kidney disease, does it?

MR. McROBBIE: You mean, like a negative value? No, it would not. The way the claim is written it wouldn't. Let me read it. As drafted, the claim does not require the person to already have kidney disease, yes.

JUDGE GRIMES: Thank you.

MR. McROBBIE: Okay. The primary reference applied by the examiner is Gorski. And just to be sure everyone knows we're talking about the right reference, the name Gorski is listed, not on the first page of the reference but on the last page of the reference. So I want to make sure we're all looking at the same page. It is this Clinical Chemistry 43, number 1, 1997. Okay? Great.

We contend that the Gorski reference has been misapplied by the Examiner simply because it has been misinterpreted. It has a fairly short reference, but if segments of the reference are taken simply out of context without reading the entire reference, I think it is very easy to misapply Gorski. So let's take a look at it.

The main goal of Gorski has nothing to do with a diagnosis of kidney disease. What Gorski has to do with is finding out how accurate a certain test is, which involves a certain FABP for evaluating, not kidney disease, but heart disease. Or I believe it says infarction. We'll just say heart disease. Okay?

The protein that is measured in Gorski is heart-type FABP. So H-FABP and not L-FABP. I'm going to come back as to why we contend it is H-FABP, but I want to talk about Gorski in a bigger sense first.

The test which is actually summarized at the very beginning of Gorski explains that FABP, which is heart-type FABP, is released from the heart early after the onset of infarction, whereas its plasma concentration increases manyfold. So the marker for purposes of evaluation of a patient after infarction is, in fact, this H-FABP.

Now, the level of that test is important and the concentration of FABP is going to be influenced not just by the severity of the infarction itself but on how fast the body clears the protein from the bloodstream.

In this case they're measuring the plasma. So it is, how fast is the body going to clear it from the bloodstream? And what is the main vehicle by which we remove a lot of these proteins from the bloodstream? It's the kidneys.

So Gorski is interested in finding out how accurate is the test when you're dealing with somebody whose kidneys are already damaged. All right? How accurate can the test actually be when somebody is not properly clearing these proteins from the blood? It is not just the kidneys, of course. The muscles and skeletal structure do clearance as well.

So Gorski is interested in evaluating a subset of a population, everybody who already is diagnosed with having some type of kidney disease, in order to find out how accurate this test regarding H-FABP is for infarction, not for diagnosis of kidney disease.

If you take a look at the end of the Gorski reference, page 195, and they say serial monitoring of the plasma FAB concentration can also be used to estimate infarct size.

However, our results indicate that if the myocardial infarct occurred in a patient with chronic renal failure, the plasma FAB concentration would be relatively higher than a patient with intact kidneys, thus leading to overestimation of its size.

So what is going on here is at first blush it might seem, and I believe this is the way that the Examiner is reading the reference, that, in fact,

Gorski is interested in measuring FABP, which is H-FABP, not L-FABP, for purposes of renal patients. But that is actually not the case.

In fact, it is this larger test of, is H-FABP a good marker for infarct or for heart disease? Because we need to find out in this certain subset of patients, in fact, if we're overestimating or maybe even providing false positives. Okay.

So Gorski is not interested in -- of course is interested in renal failure or in patients with kidney disease but not for a purpose of diagnosis. It is for a purpose of evaluating heart disease patients. That is the main distinction upon which I think we could end the hearing right now.

But, in fact, there is further distinctions in Gorski. Gorski does not deal with L-FABP. In fact, Gorski deals with H-FABP. Now, these sound very similar. They're both fatty acid binding proteins. But they are very far apart.

They are entirely different molecules. There are several types of FABPs, and I think they're names are inconvenient at best because they were named based upon the tissues that they were originally isolated from.

So you end up with heart type, liver type, kidney type. I think there may actually be nine -- in some of the references up to nine. Some references say seven FABPs; other references say nine FABPs. Okay?

But if we read Gorski, Gorski starts off in the second sentence, heart and skeletal muscles contain the same type of FABP referred to as heart type, H-FABP.

Later on when Gorski references in the middle of page 194 a particular test, plasma FABP concentration was measured by a sensitive

noncompetitive sandwich ELISA and references this reference number 4, which is a Wodzig reference.

We attached it to our responses and to the Brief. And Wodzig is interested in measuring what? H-FABP. The entirety of the disclosure is designed to measure H-FABP.

So here we have a misinterpretation of Gorski where, in fact, Gorski is not interested in diagnosis of kidney disease but, in fact, evaluating whether or not a test for heart disease is, in fact, as accurate as we believed.

And not surprisingly Gorski is measuring H-FABP. Why? Because he is not interested in the particular kidney function of a patient or diagnosing kidney disease but rather heart disease. Okay?

So once all of the facts are laid out, it is actually very straightforward. Gorski is measuring H-FABP for purposes of evaluation of heart disease.

So if we can flip back to our claim 16, I again want to highlight we are detecting liver-type fatty acid protein, L-FABP. We are diagnosing or prognosing kidney disease. Okay? These two particular elements are completely absent in combination in the Gorski reference.

The next reference, Maatman. There has been a lot said about Maatman. And, in fact, Maatman doesn't cure these two deficiencies. Maatman goes a long way to describing different molecular identifications for L- and H-FABP.

In fact, there is a troubling -- we might as well go right to it -- there is a troubling statement that I believe the Examiner has misinterpreted again in the Maatman reference.

At the top of top of -- top right-hand side page 289, Maatman says the liver-type FABP. All right? And I'm going to agree with him this time. It is L. He is not saying L and meaning H. Maatman actually means liver type, L-FABP. Also binds to some drugs and may in this way prevent nephrotoxicity.

Now, this is speculation. The beginning of the sentence, two sentences prior to that, Maatman says we can only speculate on the physiological relevance of the two FABP types in the kidney. And the fact that L-FABP binds some drugs leads Maatman to decide or to speculate that this may in some way prevent nephrotoxicity.

Okay. What is nephrotoxicity? All right? Now, I'm not going right to the issue and say, well, Maatman implicates L-FABP for the diagnosis of kidney disease because that is simply not what he is doing. There are two distinctions. First, there is speculation and we can talk about whether that speculation is enough to provide motivation to one of skill in the art to start doing things.

But more importantly, nephrotoxicity has nothing to do with kidney disease. In fact, it has to do -- it is a noun that describes the action of a drug, whether a drug is damaging to the kidneys. Okay?

So this sentence makes sense. Maatman says, well, L-FABP binds some drugs. Okay? All right? Many of those drugs are going to be detrimental to the kidney.

And so by binding these drugs perhaps in some way they are preventing nephrotoxicity. In fact, they're preventing these drugs from

doing bad things to the kidneys. This is a long way from linking L-FABP with the diagnosis of kidney disease. Okay?

There is a third reference that is cited, the Simon reference. But again, I want to highlight the link between the diagnosis or prognosis of kidney disease. We have kidney disease in my left hand and I'm tying it to detecting this particular L-FABP. All right?

Gorski is deficient. Maatman is deficient. And likewise, the Simon reference is also deficient. So yes I've talked about the references singularly, but they all have the same deficiency, this link between the diagnosis or prognosis of kidney disease and L-FABP.

So in the end, in fact, we have this line of deficiency which runs through all the references and should negate a prima facie case of obviousness. The limitations simply are not there, but we can go further, if you'd like.

JUDGE SCHEINER: I think we do understand the issue.

MR. McROBBIE: Okay. So I'd like to touch -- or would you like me to stop or would you like me to --

JUDGE SCHEINER: I just wanted to let you know that you have a couple of minutes and I do think we do understand the issue, but anything you want to add is fine.

Do you have any questions?

MR. McROBBIE: There are two particular things I would like to add and the first deals with the negative disclosure in Gorski. We addressed it at page 22 of the Brief. I won't go into great detail on it.

But there is a quote on page 194, right column, first paragraph, lines 10 through 14. Not lines 10 through 14 of the first paragraph but lines 10 through 14 of the right column and table 1 of Gorski.

Neither plasma FABP nor plasma myoglobin concentrations showed a correlation with the period of dialysis or urea or creatinine concentration in plasma. Now remember, the FABP is H-FABP. Okay?

And Gorski is saying that under analysis with dialysis, urea and creatinine concentrations are going down. Urea and creatinine are commonly used as markers for kidney disease. But in fact, plasma FABP has no correlation with the dialysis.

So why would that be a good indication of kidney health, H-FABP? So once we look at it, in fact, Gorski is pushing us away from utilizing FABP of any type, certainly H-FABP for the diagnosis of kidney disease.

Second thing I want to mention is there are two declarations on the record. One deals with long-felt need and the other deals with unexpected results.

So all of this being said, the argument is the Examiner has failed to present a prima facie case of obviousness based upon the discussion in the brief and today.

Even given -- even hypothetically admitting that the Examiner has prevented a prima facie case of obviousness, which I'm not doing, we still have unexpected results, which would legally rebut any hypothetical prima facie case of obviousness.

So we urge the Board to reconsider the Examiner's rejections. In fact, reverse the Examiner. Thank you. That is all.

JUDGE SCHEINER: Thank you for coming in.

(Whereupon, the proceedings at 1:18 p.m. were concluded.)